

EXHIBIT 31

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In a recent article, T.P. Clement (2010, hereafter referred to as TPC) discusses the complexities and limitations of “hindcasting” models and criticizes the use of complex models when undertaking investigations of subsurface reactive transport processes. TPC implies that complex numerical models that simulate reactive transport processes in groundwater are likely if not always an inappropriate tool to apply to “hindcasting” investigations and that scientists and engineers who implement these investigations using such models are somehow not aware of the technical and scientific complexities and limitations of such methods and approaches (p. 625). To illustrate his point of view, TPC uses a case study of an ongoing health study of exposure to volatile organic compounds (VOCs) in drinking water at U.S. Marine Corps Base Camp Lejeune, North Carolina (hereafter referred to as the case-control health study at Camp Lejeune). The article presents some thought-provoking points-of-view. However, we believe there is a lack of detail on several key issues that require specificity and clarification, particularly with respect to modeling approaches and methods, the physics of contaminant occurrence and reactive transport in the subsurface, and agency policies for the review and dissemination of data and reports. We thank the editors of *Ground Water* for allowing a multidisciplinary team

"Complexities in Hindcasting Models—When Should We Say Enough Is Enough," by T. Prabhakar Clement, v. 49, no. 5: 620–629.

Comment by Morris L. Maslia¹, Mustafa M. Aral², Robert E. Faye^{3,4}, Walter M. Grayman⁵, René J. Suárez-Soto⁶, Jason

of scientists and engineers working on the Camp Lejeune case-control health study the opportunity to discuss and respond to the TPC *Ground Water* Issue Paper.

"Hindcasting" vs. Historical Reconstruction

TPC defines "hindcasting" as the use of models for predicting the past to understand and resolve historical problems (p. 621). This definition, we believe, is extremely narrow and does not address the significantly broader and multidisciplinary area of exposure assessment, which includes a variety of scientific disciplines such as environmental science, epidemiology, and toxicology. Rather, we believe a more correct term than "hindcasting" is that of *historical reconstruction*, which seeks to provide estimates of contaminant concentrations in drinking water (or other environmental media) when direct, past knowledge of contaminant concentrations is limited or unavailable. Characteristically, historical reconstruction includes the application of simulation tools, such as models, to re-create or represent past conditions. A plethora of examples that describe successful historical reconstruction analyses exist in the published literature (Rodenbeck and Maslia 1998; McLaren/Hart-ChemRisk 2000; Costas et al. 2002; Reif et al. 2003; Kopecky et al. 2004; Maslia et al. 2005; Sahmel et al. 2010). Application of historical reconstruction methods and approaches to the case-control health study at Camp Lejeune recognized and required the collective expertise of team members with diverse skills and knowledge and did not focus on one discipline, such as groundwater modeling, as implied in the TPC article.

Historical reconstruction, by definition, does not preclude the use of current or present-day sources of information. In fact, successful historical reconstruction utilizes all pertinent sources of information, historical, and present-day (Maslia et al. 2000; Sahmel et al. 2010). TPC also states there are unique issues and challenges related to "hindcasting efforts that use complex models" (p. 621), apparently because no present opportunity exists to collect historical data. He fails to mention that a calibrated "hindcasting" model can just as easily be applied to the simulation of future events as well as past conditions. In fact, whether a particular model simulates past events ("hindcasting") or future events (forecasting), generic issues related to model development, calibration, and analyses of uncertainty of results are similar for both models. The calibration of a model must either stand or fall on its own merits, without the benefit of future data collection that may be accomplished later in time or the lost opportunity for data collection previously foregone. At the time of calibration, when model results are provided to policy makers, a "hindcasting" model is *not* uniquely disadvantaged compared with a forecasting model just because model predictions are historical rather than latter in time. Few, if any, policy makers or the public would accept the premise that policy decisions must be delayed for several years or several decades to

further validate an existing model when a decision must be forthcoming.

Application of "Complex" Models vs. "Simple" Models to Simulate Subsurface Reactive Processes

The Agency for Toxic Substances and Disease Registry (ATSDR) is directed by congressional mandate to perform specific functions concerning the effect on public health of hazardous substances in the environment—health studies being a specific example of this mandate (<http://www.atsdr.cdc.gov/about/index.html>). ATSDR seeks to advance the science of environmental public health by: (1) collecting, analyzing, and summarizing data related to environmental exposures and health and (2) conducting research to identify associations between environmental exposures and health risk. ATSDR's case-control health study and water-modeling investigations at Camp Lejeune include major components of data collection and analysis as well as research. To complete the health study at Camp Lejeune, ATSDR water-modeling investigations were tasked to determine (1) arrival date(s) of contaminants at water-supply wells; (2) mean monthly concentrations of contaminants arriving at base water treatment plants (WTPs) from individual wells; (3) mean monthly concentration of contaminants distributed to base housing areas; and (4) the reliability of and confidence in the simulated results (Maslia et al. 2007, 2009a, 2009b). ATSDR completed these tasks by applying the concept and methodology of *historical reconstruction*. These results are designed to provide epidemiologists with historical monthly concentrations of contaminants in drinking water at Camp Lejeune to evaluate the effects of exposure to contaminated water supplies with respect to specific birth defects (neural tube defects, cleft lip, and cleft palate) and childhood cancers (leukemia and non-Hodgkin's lymphoma).

TPC suggests that because of limited information and data and the complex nature of reactive transport processes in the subsurface, simpler models should be used. We point out, however, that simpler models will not necessarily reduce the level of uncertainty or meet project needs. It is our view that the most *appropriate* model(s) that can provide the needed information, rather than the simplest model, should be used. Thus, if a conceptually simpler model is an *appropriate* model that can meet the requirements of the Camp Lejeune case-control health study, we are in agreement that it should be applied during the historical reconstruction process. This approach is applied to all ATSDR water-modeling investigations. TPC further suggests that model complexity should be limited to a level consistent with a level of available data and invokes the notion of model parsimony or "Occam's razor" to support this point of view (p. 625). TPC's statement contradicts the fundamental precept of "Occam's razor" which, with respect to scientific thought and reasoning, requires that explanatory factors are not to be

multiplied beyond necessity. Thus, selection of a “simple” or “complex” model to simulate reactive transport processes in groundwater, according to “Occam’s razor,” should be based on study objectives, not the “level” or availability of supporting data. Whether or not sufficient data are available to completely complement model development and calibration becomes apparent when a degree of uncertainty is assigned to simulation results.

With respect to reconstructing historical groundwater VOC concentrations at Camp Lejeune, “simple” models, by definition, probably imply the application of analytical fate and transport codes. Such “simple” models are limited to—among other limiting assumptions—uniform flow fields and constant velocities. Consequently, these analytical (“simple”) models neither assess the transient aspects of water-supply well operations nor determine consecutive monthly contaminant concentrations in these wells—a goal and requirement of the case-control health study at Camp Lejeune.

While questioning ATSDR’s historical reconstruction approach for not using “simple” models, TPC appears to contradict himself by implying that ATSDR’s historical reconstruction analyses were not sufficiently complex to account for multiple competing biological-chemical processes (p. 625). After describing various complex research models that may address these complexities (e.g., incorporation of carbon limitations, modeling interactions between carbon and terminal electron acceptors), TPC concludes that such research models require extensive biochemical field data (p. 625). Thus, using “simple” models would probably always preclude consideration and simulation of complex biochemical degradation processes.

Correction and Clarification of Specific Contaminant Data Analyses and Modeling Issues

Objective of the Water-Modeling Effort

The TPC article implies that the objective for water modeling supporting the case-control health study at Camp Lejeune was for “policy-making” purposes, to advance the research interests (and funding) of the water modelers, or to satisfy politicians and citizens groups (p. 626). This is *not* the case. The water modeling was requested by ATSDR epidemiologists who required monthly drinking water contamination estimates to assess associations between in utero exposures by month and trimester and specific birth defects and childhood cancers. It is standard practice in epidemiological studies of adverse reproductive outcomes to assess exposures (whether environmental, occupational, or diet risk factors) at the monthly or trimester level (Rothman et al. 2008, 602-603).

Characterization of the Contaminant Source

TPC characterizes tetrachloroethylene (PCE) contamination in groundwater at the ABC One-Hour Cleaners

site and at Tarawa Terrace base housing as a “free-phase” or “pure-phase” dense, nonaqueous-phase liquid [DNAPL (p. 5)]. This characterization directly contradicts and misrepresents field concentration data presented by Faye and Green (2007) and in other reports and documents (Shiver 1985; Weston 1992, 1994) that describe PCE and other contaminants in the subsurface in the vicinity of Tarawa Terrace and ABC One-Hour Cleaners. Those reports and documents unequivocally describe the PCE in groundwater in the vicinity of ABC One-Hour Cleaners as “dissolved-phase” PCE. As noted by Keuper and Davies (2009), assessing for the presence of DNAPL must be made using a weight-of-evidence approach with multiple lines of evidence combining to form either a positive or a negative determination. Using one groundwater sample point with a concentration of 12,000 µg/L (as TPC apparently does) and a solubility in excess of 150,000 µg/L (Pankow and Cherry 1996; Lawrence 2007; Clement 2011), does *not* constitute a weight-of-evidence approach for a positive determination for the presence of DNAPL in soil or groundwater at Tarawa Terrace and vicinity. Rather, the weight-of-evidence approach using all site data results in a negative determination for the presence of DNAPL. It is noteworthy that more than 100 soil-boring and 140 groundwater samples were collected in the immediate vicinity of the ABC One-Hour Cleaners at depths ranging from a few feet to more than 60 feet below land surface. These data, which were tabulated and described in detail by Faye and Green (2007, Figure E2, Tables E5 and E7), did not indicate any free-phase DNAPL. Thus, while the one data value cited by TPC (12,000 µg/L) may be indicative of a contaminant source, it is definitely not indicative of free-phase DNAPL at ABC One-Hour Cleaners and Tarawa Terrace and vicinity. Furthermore, in describing the disposal practices from the ABC One-Hour Cleaners, TPC states that free-phase PCE (DNAPL) was disposed into a septic tank (p. 624). What TPC did not state is that the cleaners also continuously discharged wash and wastewater to the septic tank, thereby continuously diluting the PCE (Faye and Green 2007).

The characterization by TPC of PCE in the vicinity of ABC One-Hour Cleaners as a DNAPL is further discredited by the process selected by government agencies to remediate the PCE contamination in the groundwater. Processes selected to remediate free-phase (DNAPL) PCE in groundwater are totally different from processes used to remediate dissolved-phase PCE in groundwater. The remediation process currently in progress at the ABC One-Hour Cleaners and at Tarawa Terrace is conducted under the auspices of the U.S. Environmental Protection Agency (USEPA) and was approved by the North Carolina Department of Environment and Natural Resources (NCDENR). This process is correctly described as “groundwater extraction by wells and treatment by air stripping”—pump-and-treat (NCDENR 2003; Weston Solutions Inc. 2005, 2007). This remediation process is appropriate only for dissolved-phase PCE—not for DNAPL PCE.

Degradation Products of PCE

The biodegradation products of PCE are trichloroethylene (TCE), 1,1-dichloroethylene (1,1-DCE), *trans*- and *cis*-1,2-DCE, vinyl chloride, and ethene (Lawrence 2007; Wang and Aral 2008). As pointed out by TPC, our multispecies simulations using the TechFlowMP code did not consider *cis*-1,2-DCE as a degradation product. Although some scientific literature indicates that *cis*-1,2-DCE is the predominant product of TCE reduction under in situ groundwater conditions (NRC 2009, 49), the primary byproduct of the TCE bioreaction (biodegradation) highly depends on the chemical-biological conditions (especially microorganisms and nutrients) at contaminated sites (Bradley 2003), meaning that the biological degradation of TCE in the subsurface is highly site-specific. For example, Christiansen et al. (1997) and Miller et al. (2005) reported that the anaerobic biological degradation of TCE produced more *trans*-1,2-DCE than *cis*-1,2-DCE. At the TCE-contaminated site in Key West, Florida, the ratio of *trans*-1,2-DCE to *cis*-1,2-DCE was greater than 2 (SWMU9 2002). Griffin (2004) reported that the ratio could reach up to 3.5, based on field data for several sites, including Tahquamenon River, MI; Red Cedar River, MI; Pine River, MI; and Perfume River, Vietnam.

To calibrate reactive transport models at Tarawa Terrace and vicinity, limited field data regarding the concentrations of PCE, TCE, and *trans*-1,2-DCE were available and provided by Faye and Green (2007). TPC apparently ignored or was not aware of these data, although he frequently cites the reference by Faye and Green (2007) in the *Ground Water* article. Review of degradation byproduct data analyses, provided to ATSDR by the Department of the Navy, U.S. Marine Corps, the NCDENR, and others indicated that the predominant degradation byproduct of TCE at Tarawa Terrace and vicinity was *trans*-1,2-DCE (Faye and Green 2007, Tables E2 and E7). Because the primary byproduct of the biological degradation of TCE depends on site-specific conditions, selecting *trans*-1,2-DCE instead of *cis*-1,2-DCE as the primary TCE-bioreaction-byproduct in the study area was clearly the appropriate choice.

Model Calibration

The TPC article states that the Tarawa Terrace groundwater fate and transport model were calibrated to a limited number of data points, which are PCE levels measured in finished water samples collected in the early 1980s (p. 622). The fact is that a four-stage calibration process was used and compared with published field data at every calibration stage. Specifically, these four stages are (Maslia et al. 2007)

- Stage 1: a predevelopment calibration of the groundwater flow model, which compared simulated and measured predevelopment water levels in monitor wells (Faye and Valenzuela 2007, Figure C9).
- Stage 2: a transient calibration of the groundwater flow model, which compared simulated and transient

water levels in monitor and supply wells (Faye and Valenzuela, Figures C10 through C17 and C20),

- Stage 3: a groundwater fate and transport model, which compared simulated and measured PCE concentrations in water-supply wells (Faye 2008, Table F13 and Figures F12 through F17), and
- Stage 4: a mixing model calibration, which compared computed and measured PCE concentrations in finished water at the Tarawa Terrace WTP (Maslia et al. 2007, Table A10 and Figure A12).

TPC also implies that reactive transport model results were presented without calibrating to degradation product field data (p. 622). Calibration field data were not presented by TPC in his Figure 3 (taken from Maslia et al. 2007, Figure A19). However, available field data used for calibration were presented by Faye and Green (2007) and were compared with simulation results in Jang and Aral (2008, Figures G6 and G10).

Research Models vs. Public Domain Codes

TPC (p. 622) states that ATSDR used an advanced research code TechFlowMP (Jang and Aral 2008) to predict (simulate) the concentration of PCE along with degradation products TCE, *trans*-1,2-DCE, and vinyl chloride and that applying research codes on high-visibility projects is not a good idea (p. 626). It is important to note that public-domain/open-source codes such as MODFLOW and MT3DMS were developed under the auspices of U.S. government-sponsored research programs and were once classified as “research codes.” What then constitutes an acceptable model code, be it applied to a site of interest or a “high-profile site”? The answer may be found in Jakeman et al. (2006) who propose and describe 10 iterative steps in development and evaluation of environmental models. Thus, model validation (verification) should not be determined by the number of practitioners that use and apply a particular model (e.g., “consulting companies”), as implied by TPC (p. 626). Rather, models should be validated (verified) by following a consistent and defensible development protocol and comparing model predictions to known mathematical (analytical) solutions and site-specific field data when available. The TechFlowMP code was validated using just such a process. TechFlowMP is open-source and can be accessed through the website of the Multimedia Environmental Simulations Laboratory at Georgia Tech (<http://mesl.ce.gatech.edu/>). Additional application and testing of the code is welcomed and encouraged.

Note as well the use and application of specialized codes to address specific problems, including problems that routinely or commonly used codes do not or cannot address are not shunned by government-based scientific organizations, but rather it is recognized and encouraged (USEPA 2009). The point being that the most *appropriate* model should be applied to characterize a system, not necessarily, the most popular or frequently used model. This is the modeling philosophy and approach that

ATSDR used when applying any of the models (including the TechFlowMP model) to simulate subsurface conditions at ABC One-Hour Cleaners and Tarawa Terrace and vicinity.

Uncertainty and Variability of Simulation Results

All modeling analyses have “inherent” uncertainties. ATSDR openly acknowledges this concept. Uncertainty is not limited solely to the historical reconstruction analyses of Tarawa Terrace as critiqued by the TPC article. Uncertainty is an inherent feature of all models even when useful data are plentiful. The “profound limitation” that seemed to so concern some in evaluating the ATSDR historical reconstruction analyses (NRC 2009, 50), should not be that uncertainties exist with respect to model results but that no effort is made to explain and quantify those uncertainties. In this respect, ATSDR has provided very detailed analyses of uncertainty pertinent to the Tarawa Terrace models (Maslia et al. 2007, 2009; Wang and Aral 2008).

Review and Dissemination of Water-Modeling Results

The TPC article implies that results of ATSDR’s modeling analyses were going to be used in a decision-making process by the Department of Navy (DON). Therefore, some outside body [e.g., National Research Council (NRC)] had to be assigned the responsibility to assess the complexity of analyses being used and the impact of this complexity on time and resources. This premise is incorrect. ATSDR is a *public* health agency and part of our responsibility is the dissemination of information—technical and nontechnical—using a variety of communication methods (e.g., websites, reports, and meetings) to all interested parties and stakeholders, such as those listed by TPC (p. 622). The TPC article further states that reconstructed historical concentrations were “widely disseminated to various groups” (former Camp Lejeune residents, health scientists, and congressional committees) via websites, public meetings, and reports (p. 622). These statements imply that ATSDR somehow intentionally or unintentionally avoided a rigorous external peer review of its modeling approach, methodology, and results. The facts are that every chapter report published in the Tarawa Terrace historical reconstruction report series (available at <http://www.atsdr.cdc.gov/sites/lejeune/index.html>) underwent extensive external peer review (review comments and ATSDR responses can be produced by the project officer if needed). Authors completely addressed all external peer review comments; the majority of which were accepted by the authors and included in the final published reports.

In passing, we point out that the reference to Faye and Green (2007) cited by TPC (p. 622 and p. 628) is incorrect. Faye (2007) describes the geohydrologic framework and Faye and Green (2007) describe the occurrence of contaminants in groundwater. We provide the correct citations in the References section.

Concluding Remarks

In the *Ground Water* article, TPC proposes the following idea: Should we go with a complex model or the expert opinion (simple model)? This implies there is no option but to choose one approach or the other. As engineers and scientists, we propose that applying and evaluating the results of several different approaches and types of models is often the best path. A good model will inherently include expert opinion because models are typically developed beginning with a simple conceptual model that is then transformed into a more complex model. We agree with Bredehoeft’s opinion (2010) in that the model (simple or complex) is not an end in itself, but a tool by which to organize one’s thinking and engineering judgment. In the case of the case-control health study at Camp Lejeune, models are powerful tools used to assist epidemiologists in facilitating the estimation of historical exposures during each month of the mother’s pregnancy.

Finally, the *Ground Water* article states (p. 627) that the overall reaction to the NRC report (2009) was mixed. Similar to the TPC article, the NRC report contained numerous factual errors, incorrectly characterized the contaminant PCE source, and overlooked data (that ATSDR had inventoried, compiled, and published) and other pertinent epidemiological and toxicological issues that are beyond the scope of this discussion. Although the case-control health study at Camp Lejeune is a complex endeavor, ATSDR continues to maintain the scientific credibility and thoroughness of its analyses—from both the water-modeling and epidemiological perspectives—through the use of expert panels and external peer review. It is our aim that by addressing the complex issues associated with the process of historical reconstruction in this discussion, our colleagues who have developed and applied models solely in the groundwater modeling and remediation fields, will broaden their horizons and come to appreciate the need and usefulness of extending and incorporating modeling into the multidisciplinary field of exposure assessment science.

Disclaimers

The findings and conclusions in this Discussion article are those of the authors and do not necessarily represent the views of the ATSDR.

The use of trade names and commercial sources is for identification only and does not imply endorsement by the ATSDR.

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